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**SENATE BILL 5663**

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**State of Washington**

**66th Legislature**

**2019 Regular Session**

**By** Senator Cleveland

1 AN ACT Relating to drug compounding; amending RCW 18.64.270; and  
2 reenacting and amending RCW 18.64.011.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

4 **Sec. 1.** RCW 18.64.011 and 2016 c 148 s 1 are each reenacted and  
5 amended to read as follows:

6 The definitions in this section apply throughout this chapter  
7 unless the context clearly requires otherwise.

8 (1) "Administer" means the direct application of a drug or  
9 device, whether by injection, inhalation, ingestion, or any other  
10 means, to the body of a patient or research subject.

11 (2) "Business licensing system" means the mechanism established  
12 by chapter 19.02 RCW by which business licenses, endorsed for  
13 individual state-issued licenses, are issued and renewed utilizing a  
14 business license application and a business license expiration date  
15 common to each renewable license endorsement.

16 (3) "Chart order" means a lawful order for a drug or device  
17 entered on the chart or medical record of an inpatient or resident of  
18 an institutional facility by a practitioner or his or her designated  
19 agent.

20 (4) "Closed door long-term care pharmacy" means a pharmacy that  
21 provides pharmaceutical care to a defined and exclusive group of

1 patients who have access to the services of the pharmacy because they  
2 are treated by or have an affiliation with a long-term care facility  
3 or hospice program, and that is not a retailer of goods to the  
4 general public.

5 (5) "Commission" means the pharmacy quality assurance commission.

6 (6) "Compounding" means the act of combining two or more active  
7 ingredients in the preparation of a prescription. Compounding does  
8 not include mixing, reconstitution, or other acts that are performed  
9 in accordance with directions contained in approved labeling provided  
10 by the product's manufacturer and other manufacturer directions  
11 consistent with that labeling.

12 (7) "Controlled substance" means a drug or substance, or an  
13 immediate precursor of such drug or substance, so designated under or  
14 pursuant to the provisions of chapter 69.50 RCW.

15 (8) "Deliver" or "delivery" means the actual, constructive, or  
16 attempted transfer from one person to another of a drug or device,  
17 whether or not there is an agency relationship.

18 (9) "Department" means the department of health.

19 (10) "Device" means instruments, apparatus, and contrivances,  
20 including their components, parts, and accessories, intended (a) for  
21 use in the diagnosis, cure, mitigation, treatment, or prevention of  
22 disease in human beings or other animals, or (b) to affect the  
23 structure or any function of the body of human beings or other  
24 animals.

25 (11) "Dispense" means the interpretation of a prescription or  
26 order for a drug, biological, or device and, pursuant to that  
27 prescription or order, the proper selection, measuring, compounding,  
28 labeling, or packaging necessary to prepare that prescription or  
29 order for delivery.

30 (12) "Distribute" means the delivery of a drug or device other  
31 than by administering or dispensing.

32 (13) "Drug" and "devices" do not include surgical or dental  
33 instruments or laboratory materials, gas and oxygen, therapy  
34 equipment, X-ray apparatus or therapeutic equipment, their component  
35 parts or accessories, or equipment, instruments, apparatus, or  
36 contrivances used to render such articles effective in medical,  
37 surgical, or dental treatment, or for use or consumption in or for  
38 mechanical, industrial, manufacturing, or scientific applications or  
39 purposes. "Drug" also does not include any article or mixture covered  
40 by the Washington pesticide control act (chapter 15.58 RCW), as

1 enacted or hereafter amended, nor medicated feed intended for and  
2 used exclusively as a feed for animals other than human beings.

3 (14) "Drugs" means:

4 (a) Articles recognized in the official United States  
5 pharmacopoeia or the official homeopathic pharmacopoeia of the United  
6 States;

7 (b) Substances intended for use in the diagnosis, cure,  
8 mitigation, treatment, or prevention of disease in human beings or  
9 other animals;

10 (c) Substances (other than food) intended to affect the structure  
11 or any function of the body of human beings or other animals; or

12 (d) Substances intended for use as a component of any substances  
13 specified in (a), (b), or (c) of this subsection, but not including  
14 devices or their component parts or accessories.

15 (15) "Health care entity" means an organization that provides  
16 health care services in a setting that is not otherwise licensed by  
17 the state to acquire or possess legend drugs. Health care entity  
18 includes a freestanding outpatient surgery center, a residential  
19 treatment facility, and a freestanding cardiac care center. "Health  
20 care entity" does not include an individual practitioner's office or  
21 a multipractitioner clinic, regardless of ownership, unless the owner  
22 elects licensure as a health care entity. "Health care entity" also  
23 does not include an individual practitioner's office or  
24 multipractitioner clinic identified by a hospital on a pharmacy  
25 application or renewal pursuant to RCW 18.64.043.

26 (16) "Hospice program" means a hospice program certified or paid  
27 by medicare under Title XVIII of the federal social security act, or  
28 a hospice program licensed under chapter 70.127 RCW.

29 (17) "Institutional facility" means any organization whose  
30 primary purpose is to provide a physical environment for patients to  
31 obtain health care services including, but not limited to, services  
32 in a hospital, long-term care facility, hospice program, mental  
33 health facility, drug abuse treatment center, residential  
34 habilitation center, or a local, state, or federal correction  
35 facility.

36 (18) "Labeling" means the process of preparing and affixing a  
37 label to any drug or device container. The label must include all  
38 information required by current federal and state law and pharmacy  
39 rules.

1 (19) "Legend drugs" means any drugs which are required by any  
2 applicable federal or state law or regulation to be dispensed on  
3 prescription only or are restricted to use by practitioners only.

4 (20) "Long-term care facility" means a nursing home licensed  
5 under chapter 18.51 RCW, an assisted living facility licensed under  
6 chapter 18.20 RCW, or an adult family home licensed under chapter  
7 70.128 RCW.

8 (21) "Manufacture" means the production, preparation,  
9 propagation, compounding, or processing of a drug or other substance  
10 or device or the packaging or repackaging of such substance or  
11 device, or the labeling or relabeling of the commercial container of  
12 such substance or device, but does not include the activities of a  
13 practitioner who, as an incident to his or her administration or  
14 dispensing such substance or device in the course of his or her  
15 professional practice, personally prepares, compounds, packages, or  
16 labels such substance or device. "Manufacture" includes the  
17 distribution of a licensed pharmacy compounded drug product to other  
18 state licensed persons or commercial entities for subsequent resale  
19 or distribution, unless a specific product item has approval of the  
20 commission. The term does not include:

21 (a) The activities of a licensed pharmacy that compounds a  
22 product on or in anticipation of an order of a licensed practitioner  
23 for use in the course of their professional practice to administer to  
24 patients, either personally or under their direct supervision;

25 (b) The practice of a licensed pharmacy when repackaging  
26 commercially available medication in small, reasonable quantities for  
27 a practitioner legally authorized to prescribe the medication for  
28 office use only;

29 (c) The distribution of a drug product that has been compounded  
30 by a licensed pharmacy to other appropriately licensed entities under  
31 common ownership or control of the facility in which the compounding  
32 takes place; or

33 (d) The delivery of finished and appropriately labeled compounded  
34 products dispensed pursuant to a valid prescription to alternate  
35 delivery locations, other than the patient's residence, when  
36 requested by the patient, or the prescriber to administer to the  
37 patient, or to another licensed pharmacy to dispense to the patient.

38 (22) "Manufacturer" means a person, corporation, or other entity  
39 engaged in the manufacture of drugs or devices.

1 (23) "Nonlegend" or "nonprescription" drugs means any drugs which  
2 may be lawfully sold without a prescription.

3 (24) "Person" means an individual, corporation, government,  
4 governmental subdivision or agency, business trust, estate, trust,  
5 partnership or association, or any other legal entity.

6 (25) "Pharmacist" means a person duly licensed by the commission  
7 to engage in the practice of pharmacy.

8 (26) "Pharmacy" means every place properly licensed by the  
9 commission where the practice of pharmacy is conducted.

10 (27) "Poison" does not include any article or mixture covered by  
11 the Washington pesticide control act (chapter 15.58 RCW), as enacted  
12 or hereafter amended.

13 (28) "Practice of pharmacy" includes the practice of and  
14 responsibility for: Interpreting prescription orders; the  
15 compounding, dispensing, labeling, administering, and distributing of  
16 drugs and devices; the monitoring of drug therapy and use; the  
17 initiating or modifying of drug therapy in accordance with written  
18 guidelines or protocols previously established and approved for his  
19 or her practice by a practitioner authorized to prescribe drugs; the  
20 participating in drug utilization reviews and drug product selection;  
21 the proper and safe storing and distributing of drugs and devices and  
22 maintenance of proper records thereof; the providing of information  
23 on legend drugs which may include, but is not limited to, the  
24 advising of therapeutic values, hazards, and the uses of drugs and  
25 devices.

26 (29) "Practitioner" means a physician, dentist, veterinarian,  
27 nurse, or other person duly authorized by law or rule in the state of  
28 Washington to prescribe drugs.

29 (30) "Prescription" means an order for drugs or devices issued by  
30 a practitioner duly authorized by law or rule in the state of  
31 Washington to prescribe drugs or devices in the course of his or her  
32 professional practice for a legitimate medical purpose.

33 (31) "Secretary" means the secretary of health or the secretary's  
34 designee.

35 (32) "Shared pharmacy services" means a system that allows a  
36 participating pharmacist or pharmacy pursuant to a request from  
37 another participating pharmacist or pharmacy to process or fill a  
38 prescription or drug order, which may include but is not necessarily  
39 limited to preparing, packaging, labeling, data entry, compounding  
40 for specific patients, dispensing, performing drug utilization

1 reviews, conducting claims adjudication, obtaining refill  
2 authorizations, reviewing therapeutic interventions, or reviewing  
3 chart orders.

4 (33) "Wholesaler" means a corporation, individual, or other  
5 entity which buys drugs or devices for resale and distribution to  
6 corporations, individuals, or entities other than consumers.

7 **Sec. 2.** RCW 18.64.270 and 2013 c 146 s 2 are each amended to  
8 read as follows:

9 (1) Every proprietor of a wholesale or retail drug store shall be  
10 held responsible for the quality of all drugs, chemicals or medicines  
11 sold or dispensed by him or her except those sold in original  
12 packages of the manufacturer and except those articles or  
13 preparations known as patent or proprietary medicines.

14 (2) (~~Any~~) Medicinal products or preparations that are  
15 compounded for patient administration or distribution to a licensed  
16 practitioner for patient use or administration shall, at a minimum,  
17 meet the standards of the official United States pharmacopeia as it  
18 applies to nonsterile (~~products~~) and sterile administered products  
19 and preparations.

20 (3) The commission shall adopt rules identifying which chapters  
21 or provisions of the official United States pharmacopeia are  
22 applicable to nonsterile and sterile products and preparations  
23 compounded for patient administration or distribution to a licensed  
24 practitioner for patient use or administration.

25 (4) Any person who shall knowingly, willfully or fraudulently  
26 falsify or adulterate any drug or medicinal substance or preparation  
27 authorized or recognized by an official compendium or used or  
28 intended to be used in medical practice, or shall willfully,  
29 knowingly or fraudulently offer for sale, sell or cause the same to  
30 be sold for medicinal purposes, is guilty of a misdemeanor, and upon  
31 conviction thereof shall be punished by a fine in any sum not less  
32 than seventy-five nor more than one hundred and fifty dollars or by  
33 imprisonment in the county jail for a period of not less than one  
34 month nor more than three months, and any person convicted a third  
35 time for violation of this section may suffer both fine and  
36 imprisonment. In any case he or she shall forfeit to the state of  
37 Washington all drugs or preparations so falsified or adulterated.

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